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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|--|----------------------|----------------------|---------------------|-------------------|--|
| 10/849,039 | 05/20/2004 | James T. Dalton | P-5235-US14 | 7024 | |
| 27130 7 | 7130 7590 01/26/2006 | | EXAMINER | | |
| EITAN, PEARL, LATZER & COHEN ZEDEK LLP | | | KUMAR, SH | KUMAR, SHAILENDRA | |
| 10 ROCKEFELLER PLAZA, SUITE 1001 NEW YORK, NY 10020 | | J1 | ART UNIT | PAPER NUMBER | |
| • | | | 1621 | | |

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | |
|---|---|--|---|--|--|--|--|
| Office Action Summary | | 10/849,039 | DALTON ET AL. | | | | |
| | | Examiner | Art Unit | | | | |
| | | SHAILENDRA KUMAR | 1621 | | | | |
| | - The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | | |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, | | | | | | | |
| WHIC - Exter after - If NO - Failu Any r | CHEVER IS LONGER, FROM THE MAILING sions of time may be available under the provisions of 37 CFF SIX (6) MONTHS from the mailing date of this communication. Period for reply is specified above, the maximum statutory per to reply within the set or extended period for reply will, by streply received by the Office later than three months after the med patent term adjustment. See 37 CFR 1.704(b). | S DATE OF THIS COMMUNICATION R 1.136(a). In no event, however, may a reply be tire riod will apply and will expire SIX (6) MONTHS from atute, cause the application to become ABANDONE | N. nely filed the mailing date of this communication. ED (35 U.S.C. § 133). | | | | |
| Status | | | | | | | |
| 1)🖾 | Responsive to communication(s) filed on 20 | 0 May 2004. | | | | | |
| · — | This action is FINAL . 2b)⊠ This action is non-final. | | | | | | |
| 3)□ | | | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Disposition of Claims | | | | | | | |
| 4)⊠ | 4)⊠ Claim(s) <u>1-95</u> is/are pending in the application. | | | | | | |
| | 4a) Of the above claim(s) <u>33,34,38-51,65-67,76-78 and 82-95</u> is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| · | Claim(s) <u>1-32,35-37,52-64,68-75 and 79-8</u> | <u>í</u> is/are rejected. | | | | | |
| - | Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | | |
| Application Papers | | | | | | | |
| 9) 🗌 🤄 | The specification is objected to by the Exam | niner. | | | | | |
| 10)⊠ The drawing(s) filed on <u>20 May 2004</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority u | ınder 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| | the attached detailed office dotton for a | not of the sertified depice flot receive | | | | | |
| Attachmen | t(s) | | | | | | |
| | e of References Cited (PTO-892) | 4) Interview Summary | | | | | |
| 3) Inform | e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB r No(s)/Mail Date | | ate Patent Application (PTO-152) | | | | |

Application/Control Number: 10/849,039

Art Unit: 1621

DETAILED ACTION

This office action is in response to applicants' communication filed on 1/17/06.

Claims 1-95 are pending in this application.

Applicants' election of Group I, claims 1-32, 35-37, 52-64, 68-75 and 79-81 are acknowledged herewith. Inasmuch as applicants have not otherwise mentioned, it is presumed that the election is without traverse. With respect to the rejoinder, once elected claims are found allowable, method claims within the scope of allowed compounds claimed would be rejoined and allowed.

Claims 33-34, 38-51, 65-67, 76-78 and 82-95 stand withdrawn from the consideration, being drawn to the non elected invention.

Drawings

1. The drawings were received on 5/20/2004. These drawings are acceptable.

Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 63, 69-75 and 79-81 recites the limitation either three substituents on the left hand side phenyl ring or have a substituent F and hydroxyl on the right side phenyl ring, whereas, claim 52 has only one substituent on the right hand phenyl ring and two substituents on the left hand side phenyl ring. There is insufficient antecedent basis for this limitation in the claim.

Application/Control Number: 10/849,039 Page 3

Art Unit: 1621

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 7. Claims 1-32, 35-37, 52-64, 68-75 and 79-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tucker(US 4,636,505) or Miller et al(US 6,019,957).

Application/Control Number: 10/849,039

Art Unit: 1621

Miller et al, column 6, line 40 through column 8, line 63, or Tucker column 1, line 30 through column 3, line 20, teach structurally similar compounds and composition as claimed herein. Note, Miller et a, R1 through R6 are similar to those claimed herein, R7 can be phenyl substituted, X1 can be O, A1 can be methylene and A2 can be a bond. Likewise, in Tucker, R1-R6 are similar those claimed herein, R7 can be phenyl substituted, X1 can be O etc.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to obtain compounds and composition within the generic disclosure of the references, because they are structurally so similar to the claimed compounds and composition, with the reasonable expectation of achieving a successful pharmaceutical composition, absent evidence to the contrary.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Application/Control Number: 10/849,039 Page 5

Art Unit: 1621

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 9. Claims 1-32, 35-37, 52-64, 68-75 and 79-81 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-85 of U.S. Patent No. 6,838,484, or over claims 1-10 of U.S. Patent No. 6,569,896, or over claims 1-5 of U.S. Patent No. 6,492,554. Although the conflicting claims are not identical, they are not patentably distinct from each other because various substituents as claimed herein extensively overlap those in the above patents, and one of ordinary skill in the art would have obtained compounds within the generic disclosure of the above patents, because they are structurally so similar to those claimed herein, with the reasonable expectation of achieving a successful composition, absent evidence to the contrary.
- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA -. KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/849,039 Page 6

Art Unit: 1621

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHAÌLENDRA - KUMAR Primary Examiner Art Unit 1621

S.Kumar 1/23/06